ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Faslodex 250 mg solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One pre-filled syringe contains 250 mg fulvestrant in 5 ml solution.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless to yellow, viscous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Faslodex is indicated for the treatment of postmenopausal women with estrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-estrogen therapy or disease progression on therapy with an anti-estrogen.

4.2 Posology and method of administration

Posology
Adult females (including the elderly)
The recommended dose is 250 mg at intervals of 1 month.

Paediatric patients
Faslodex is not recommended for use in children or adolescents, as safety and efficacy have not been established in this age group.

Renal impairment
No dose adjustments are recommended for patients with mild to moderate renal impairment (creatinine clearance ≥ 30 ml/min). Safety and efficacy have not been evaluated in patients with severe renal impairment (creatinine clearance < 30 ml/min), and, therefore, caution is recommended in these patients (see section 4.4).

Hepatic impairment
No dose adjustments are recommended for patients with mild to moderate hepatic impairment. However, as fulvestrant exposure may be increased, Faslodex should be used with caution in these patients. There are no data in patients with severe hepatic impairment (see sections 4.3, 4.4 and 5.2).

Method of administration
Faslodex should be administered by slow intramuscular injection into the buttock.
For detailed instructions for administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance, or to any of the other excipients.

Pregnancy and lactation (see section 4.6)
Severe hepatic impairment (see sections 4.4 and 5.2).

4.4 Special warnings and precautions for use

Faslodex should be used with caution in patients with mild to moderate hepatic impairment (see sections 4.2, 4.3 and 5.2).

Faslodex should be used with caution in patients with severe renal impairment (creatinine clearance less than 30 ml/min)

Due to the intramuscular route of administration, Faslodex should be used with caution if treating patients with bleeding diatheses, thrombocytopenia or those taking anticoagulant treatment.

Thromboembolic events are commonly observed in women with advanced breast cancer and have been observed in clinical trials with Faslodex (see section 4.8). This should be taken into consideration when prescribing Faslodex to patients at risk.

There are no long-term data on the effect of fulvestrant on bone. Due to the mechanism of action of fulvestrant, there is a potential risk of osteoporosis.

4.5 Interaction with other medicinal products and other forms of interaction

A clinical interaction study with midazolam (substrate of CYP3A4) demonstrated that fulvestrant does not inhibit CYP3A4. Clinical interaction studies with rifampicin (inducer of CYP3A4) and ketoconazole (inhibitor of CYP3A4) showed no clinically relevant change in fulvestrant clearance. Dose adjustment is therefore not necessary in patients who are receiving fulvestrant and CYP3A4 inhibitors or inducers concomitantly.

4.6 Pregnancy and lactation

Faslodex is contraindicated in pregnancy (see section 4.3). Fulvestrant has been shown to cross the placenta after single intramuscular doses in rat and rabbit. Studies in animals have shown reproductive toxicity including an increased incidence of foetal abnormalities and deaths (see section 5.3). Patients of child-bearing potential should be advised to use effective contraception while on treatment. If pregnancy occurs while taking Faslodex, the patient must be informed of the potential hazard to the foetus and potential risk for loss of pregnancy.

Fulvestrant is excreted in milk in lactating rats. It is not known whether fulvestrant is excreted in human milk. Considering the potential for serious adverse reactions due to fulvestrant in breast-fed infants, lactation is contraindicated (see section 4.3).

4.7 Effects on ability to drive and use machines

Faslodex has no or negligible influence on the ability to drive or use machines. However, since asthenia has been reported commonly with Faslodex, caution should be observed by those patients who experience this adverse reaction when driving or operating machinery.

4.8 Undesirable effects

This section provides information based on all adverse reactions from clinical trials, post-marketing studies or spontaneous reports. Approximately 47 % of patients experienced adverse reactions in the clinical trial programme. However, only 0.9 % of patients stopped therapy because of an adverse reaction. The most frequently reported adverse reactions are hot flushes, nausea, and injection site reactions. Adverse reactions listed below are classified according to frequency and System Organ Class (SOC). Frequency groupings are defined according to the following convention: Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100). Within each frequency grouping adverse reactions are reported in order of decreasing seriousness.

Table 1 Adverse Drug Reactions

SOC	Very common	Common	Uncommon
Nervous system disorders		Headache	
Gastrointestinal disorders		Vomiting, nausea and diarrhoea	
Renal and urinary disorders		Urinary tract infections	
Skin and subcutaneous tissue disorders		Rash	
Musculoskeletal and connective tissue disorders		Back pain	
Metabolism and nutrition disorders		Anorexia	
Vascular disorders	Hot flushes	Venous thromboembolism	
General disorders and administration site conditions		Asthenia Injection site reactions including injection site pain and injection site inflammation[1]	
Immune system disorders			Hypersensitivity reactions, including angioedema and urticaria
Hepatobiliary disorders		Increased Hepatic Enzymes[2]	
Reproductive system and breast disorders			Vaginal moniliasis Leukorrhea Vaginal haemorrhage

[1] injection site reactions pain is transient 7% of patients (1% of injections) when given as a single 5 ml injection.
[2] the vast majority <2xULN

4.9 Overdose

There is no human experience of overdose. Animal studies suggest that no effects other than those related directly or indirectly to anti-estrogenic activity were evident with higher doses of fulvestrant (see section 5.3). If overdose occurs, symptomatic supportive treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-estrogens, ATC code: L02BA03

Mechanism of action
Fulvestrant is a competitive estrogen receptor (ER) antagonist with an affinity comparable to estradiol. Fulvestrant blocks the trophic actions of estrogens without any partial agonist (estrogen-like) activity. The mechanism of action is associated with down-regulation of estrogen receptor protein levels.

Clinical trials in postmenopausal women with primary breast cancer have shown that fulvestrant significantly down-regulates ER protein in ER positive tumours compared with placebo. There was also a significant decrease in progesterone receptor expression consistent with a lack of intrinsic estrogen agonist effects.

Clinical safety and efficacy in advanced breast cancer
Two phase III clinical trials were completed in a total of 851 postmenopausal women with advanced breast cancer who had disease recurrence on or after adjuvant endocrine therapy or progression following endocrine therapy for advanced disease. 77% of the study population had estrogen receptor positive breast cancer. These trials compared the safety and efficacy of monthly administration of 250 mg fulvestrant versus the daily administration of 1 mg anastrozole (aromatase inhibitor).

Overall, fulvestrant at the 250 mg monthly dose was at least as effective as anastrozole in terms of time to progression, objective response, and time to death. There were no statistically significant differences in any of these endpoints between the two treatment groups. Time to progression was the primary endpoint. Combined analysis of both trials showed that 83% of patients who received fulvestrant progressed, compared with 85% of patients who received anastrozole. The hazard ratio of fulvestrant to anastrozole for time to progression was 0.95 (95% CI 0.82 to 1.10). The objective response rate for fulvestrant was 19.2% compared with 16.5% for anastrozole. The median time to death was 27.4months for patients treated with fulvestrant and 27.6 months for patients treated with anastrozole. The hazard ratio of fulvestrant to anastrozole for time to death was 1.01 (95% CI 0.86 to 1.19). Analysis of results by ER status showed that the use of fulvestrant should be restricted to patients with ER positive breast cancer.

Effects on the postmenopausal endometrium
Preclinical data do not suggest a stimulatory effect of fulvestrant on the postmenopausal endometrium (see section 5.3). A 2-week study in healthy postmenopausal volunteers treated with 20 μg per day ethinylestradiol showed that pre-treatment with 250 mg fulvestrant resulted in significantly reduced stimulation of the postmenopausal endometrium, compared to pre-treatment with placebo, as judged by ultrasound measurement of endometrium thickness

There are no data on the long-term effects of fulvestrant on the postmenopausal endometrium. No data are available regarding endometrial morphology.

In two short-term studies (1 and 12 weeks) with premenopausal patients with benign gynaecologic disease, no significant differences in endometrial thickness were observed by ultrasound measuring between fulvestrant and placebo groups.

Effects on bone
There are no long-term data on the effect of fulvestrant on bone.

5.2 Pharmacokinetic properties

Absorption
After administration of Faslodex long-acting as an intramuscular injection, fulvestrant is slowly absorbed and maximum plasma concentrations (C_{max}) are reached after about 7 days. Absorption continues for over one month, and monthly administration results in an approximate 2-fold accumulation. Steady-state levels are reached after about 6 monthly injections, with the major part of the accumulation achieved after 3-4 doses. At steady state, fulvestrant plasma concentrations are maintained within a relatively narrow range with approximately 2- to 3-fold difference between maximum and trough concentrations. After intramuscular administration, the exposure is approximately dose-proportional in the dose range 50 to 250 mg.

Distribution
Fulvestrant is subject to extensive and rapid distribution. The large apparent volume of distribution at steady state (Vd_{ss}) of approximately 3 to 5 l/kg suggests that distribution is largely extravascular. Fulvestrant is highly (99%) bound to plasma proteins. Very low density lipoprotein (VLDL), low

density lipoprotein (LDL), and high density lipoprotein (HDL) fractions are the major binding components. No interaction studies were conducted on competitive protein binding. The role of sex hormone-binding globulin (SHBG) has not been determined.

Metabolism
The metabolism of fulvestrant has not been fully evaluated, but involves combinations of a number of possible biotransformation pathways analogous to those of endogenous steroids. Identified metabolites (includes 17-ketone, sulphone, 3-sulphate, 3- and 17-glucuronide metabolites) are either less active or exhibit similar activity to fulvestrant in anti-estrogen models. Studies using human liver preparations and recombinant human enzymes indicate that CYP3A4 is the only P450 isoenzyme involved in the oxidation of fulvestrant; however, non-P450 routes appear to be more predominant *in vivo*. *In vitro* data suggest that fulvestrant does not inhibit CYP450 isoenzymes.

Elimination
Fulvestrant is eliminated mainly in metabolised form. The major route of excretion is via the faeces, with less than 1% being excreted in the urine. Fulvestrant has a high clearance, 11±1.7 ml/min/kg, suggesting a high hepatic extraction ratio. The terminal half-life ($t_{1/2}$) after intramuscular administration is governed by the absorption rate and was estimated to be 50 days.

Special populations
In a population pharmacokinetic analysis of data from phase III studies, no difference in fulvestrant's pharmacokinetic profile was detected with regard to age (range 33 to 89 years), weight (40-127 kg) or race.

Renal impairment
Mild to moderate impairment of renal function did not influence the pharmacokinetics of fulvestrant to any clinically relevant extent.

Hepatic impairment
The pharmacokinetics of fulvestrant has been evaluated in a single-dose clinical trial conducted in subjects with mild to moderate hepatic impairment (Child-Pugh class A and B). A high dose of a shorter duration intramuscular injection formulation was used. There was up to about 2.5-fold increase in AUC in subjects with hepatic impairment compared to healthy subjects. In patients administered Faslodex, an increase in exposure of this magnitude is expected to be well tolerated. Subjects with severe hepatic impairment (Child-Pugh class C) were not evaluated.

5.3 Preclinical safety data

The acute toxicity of fulvestrant is low.

Faslodex and other formulations of fulvestrant were well tolerated in animal species used in multiple dose studies. Local reactions, including myositis and granulomatoma at the injection site were attributed to the vehicle but the severity of myositis in rabbits increased with fulvestrant, compared to the saline control. In toxicity studies with multiple intramuscular doses of fulvestrant in rats and dogs, the anti-estrogenic activity of fulvestrant was responsible for most of the effects seen, particularly in the female reproductive system, but also in other organs sensitive to hormones in both sexes.

In dog studies following oral and intravenous administration, effects on the cardiovascular system (slight elevations of the S-T segment of the ECG [oral], and sinus arrest in one dog [intravenous]) were seen. These occurred at exposure levels higher than in patients (C_{max} > 40 times) and are likely to be of limited significance for human safety at the clinical dose.

Fulvestrant showed no genotoxic potential.
Fulvestrant showed effects upon reproduction and embryo/foetal development consistent with its anti-estrogenic activity, at doses similar to the clinical dose. In rats, a reversible reduction in female fertility and embryonic survival, dystocia and an increased incidence of foetal abnormalities including tarsal flexure were observed. Rabbits given fulvestrant failed to maintain pregnancy. Increases in

placental weight and post-implantation loss of foetuses were seen. There was an increased incidence of foetal variations in rabbits (backwards displacement of the pelvic girdle and 27 pre-sacral vertebrae).

A two-year oncogenicity study in rats (intramuscular administration of Faslodex) showed increased incidence of ovarian benign granulosa cell tumours in female rats at the high dose, 10 mg/rat/15 days and an increased incidence of testicular Leydig cell tumours in males. Induction of such tumours is consistent with pharmacology-related endocrine feedback alterations. These findings are not of clinical relevance for the use of fulvestrant in postmenopausal women with advanced breast cancer.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96 per cent)
Benzyl alcohol
Benzyl benzoate
Castor oil

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

4 years

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Store the pre-filled syringe in the original package in order to protect from light.

6.5 Nature and contents of container

One clear type 1 glass pre-filled syringe with polystyrene plunger rod, fitted with a tamper-evident closure, containing 5 ml solution for injection.
A safety needle (SafetyGlide) for connection to the barrel is also provided.

6.6 Special precautions for disposal and other handling

Instructions for administration
Remove glass syringe barrel from tray and check that it is not damaged.
Peel open the safety needle (SafetyGlide) outer packaging. (For safety needle instructions see below).
Break the seal of the white plastic cover on the syringe Luer connector to remove the cover with the attached rubber tip cap (see Figure 1). Twist to lock the needle to the Luer connector.
Remove needle sheath.
Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.
Remove excess gas from the syringe (a small gas bubble may remain). Administer intramuscularly slowly into the buttock.
Immediately activate needle protection device upon withdrawal of the needle from patient by pushing lever arm completely forward until needle tip is fully covered (see Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate the safety needle, discard immediately into an approved sharps collector.

SafetyGlide Information from Becton Dickinson
WARNING: - Do not autoclave safety needle before use. Hands must remain behind the needle at all times during use and disposal.

Directions for Use of safety needle
Peel apart packaging of the safety needle, break the seal of the white plastic cover on the syringe Luer connector and attach the safety needle to the Luer Lock of the syringe by twisting.

Transport filled syringe to point of administration.

Pull shield straight off needle to avoid damaging needle point.

Administer injection following package instruction.
For user convenience, the needle 'bevel up' position is orientated to the lever arm, as shown in Figure 3.

Immediately activate needle protection device upon withdrawal from patient by pushing lever arm completely forward until needle tip is fully covered (Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate, discard immediately into an approved sharps collector.

Activation of the protective mechanism may cause minimal splatter of fluid that may remain on the needle after injection.

For greatest safety, use a one-handed technique and activate away from self and others.

<u>Disposal</u>
Pre-filled syringes are for single use **only**.
Any unused product or waste material should be disposed of in accordance with local requirements.

Figure 1

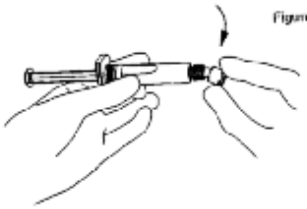
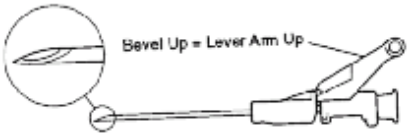


Figure 2

Activated after use

Figure 3



7. MARKETING AUTHORISATION HOLDER

AstraZeneca UK Limited
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Cheshire
SK10 4TG
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/03/269/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 March 2004
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release
AstraZeneca UK Limited
Silk Road Business Park,
Macclesfield, SK10 2NA
United Kingdom

B CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

  Medicinal product subject to medical prescription.

- **OTHER CONDITIONS**

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Faslodex 250 mg solution for injection.
fulvestrant

2. STATEMENT OF ACTIVE SUBSTANCE(S)

One pre-filled syringe contains 250 mg fulvestrant in 5 ml solution

3. LIST OF EXCIPIENTS

Ethanol (96 per cent), benzyl alcohol, benzyl benzoate and castor oil. See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection in a pre-filled syringe.
1 pre-filled syringe (5 ml)
1 safety needle (SafetyGlide)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.
For single use only.
For full instructions on the administration of Faslodex and the use of the safety needle see enclosed Instructions for Use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Store the pre-filled syringe in the original package in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

AstraZeneca UK Limited
Alderley Park
Macclesfield
Cheshire
SK10 4TG
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/03/269/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Justification for not including Braille accepted.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PRE-FILLED SYRINGE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Faslodex 250 mg solution for injection
fulvestrant
IM use

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

5 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Faslodex 250 mg solution for injection
Fulvestrant

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. WHAT FASLODEX IS AND WHAT IT IS USED FOR

Faslodex contains the active substance fulvestrant, which belongs to the group of estrogen blockers. Estrogens, a type of female sex hormones, can in some cases be involved in the growth of breast cancer.

Faslodex is used to treat advanced or metastatic breast cancer in postmenopausal women.

2. BEFORE YOU USE FASLODEX

Do not use Faslodex
- if you are allergic (hypersensitive) to fulvestrant or to any of the other ingredients of Faslodex (listed in section 6 'What Faslodex contains')
- if you are pregnant or breast-feeding
- if you have severe liver problems

Take special care with Faslodex
Tell your doctor if any of these apply to you:
- kidney or liver problems
- low numbers of platelets (which help blood clotting) or bleeding disorders
- previous problems with blood clots
- osteoporosis (loss of bone density)
- Alcoholism

Using other medicines
Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
In particular, you should tell your doctor if you are using anticoagulants (medicines to prevent blood clots).

Pregnancy and breast-feeding
You must not use Faslodex if you are pregnant. If you can become pregnant, you should use effective contraception while being treated with Faslodex.

You must not breast-feed while on treatment with Faslodex.

Driving and using machines
Faslodex is not expected to affect your ability to drive or use machines. However, if you feel tired after treatment do not drive or use machines**.**

Important information about some of the ingredients of Faslodex

This medicinal product contains 10 % w/v ethanol (alcohol), i.e. up to 500 mg per dose, equivalent to 10 ml beer or 4 ml wine per dose.
Harmful for those suffering from alcoholism.
To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

3. HOW TO USE FASLODEX

The usual dose is 250 mg fulvestrant (one 5 ml injection) given once a month.

Your doctor or nurse will give you Faslodex as a slow intramuscular injection into your buttock.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Faslodex can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:
- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Very common side effects
- Hot flushes

Common side effects
- Injection site reactions, such as pain and/or inflammation
- Headache
- Weakness and tiredness
- Nausea (feeling sick), vomiting, diarrhoea or loss of appetite
- Rash
- Urinary tract infections
- Back pain
- Increased risk of blood clots
- Abnormal levels of liver enzymes (in blood tests)

Uncommon side effects
- Allergic (hypersensitivity) reactions, including swelling of the face, lips, tongue and/or throat
- Vaginal bleeding, thick, whitish discharge and candidiasis (infection)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. HOW TO STORE FASLODEX

Store in a refrigerator (2°C – 8°C)
Keep the pre-filled syringe in the original package, in order to protect from light.

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton or syringe label after the abbreviation EXP. The expiry date refers to the last day of that month.

Your health care professional will be responsible for the correct storage, use and disposal of Faslodex.

6. FURTHER INFORMATION

What Faslodex contains
- The active substance is fulvestrant. Each pre-filled syringe (5 ml) contains 250 mg fulvestrant.
- The other ingredients are ethanol (96 per cent), benzyl alcohol, benzyl benzoate and castor oil.

What Faslodex looks like and contents of the pack
Faslodex is a clear, colourless to yellow, viscous solution in a pre-filled syringe fitted with a tamper-evident closure, containing 5 ml solution for injection A safety needle (SafetyGlide) for connection to the barrel is also provided.

Marketing Authorisation Holder
AstraZeneca UK Limited
Alderley Park
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Manufacturer
AstraZeneca UK Limited
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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Sverige
AstraZeneca AB

Tel: +46 8 553 26 000

This leaflet was last approved on

The following information is intended for healthcare professionals only:

Faslodex 250 mg/5 ml solution for injection. Pre-filled syringe.

Instructions for administration

Remove glass syringe barrel from tray and check that it is not damaged.
Peel open the safety needle (SafetyGlide) outer packaging. (For safety needle instructions see below).
Break the seal of the white plastic cover on the syringe Luer connector to remove the cover with the attached rubber tip cap (see Figure 1). Twist to lock the needle to the Luer connector.
Remove needle sheath.
Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.
Remove excess gas from the syringe (a small gas bubble may remain). Administer intramuscularly slowly into the buttock.
Immediately activate needle protection device upon withdrawal of the needle from patient by pushing lever arm completely forward until needle tip is fully covered (see Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate the safety needle, discard immediately into an approved sharps collector.

SafetyGlide Information from Becton Dickinson

WARNING: - Do not autoclave safety needle before use. Hands must remain behind the needle at all times during use and disposal.

Directions for Use of safety needle

Peel apart packaging of the safety needle, break the seal of the white plastic cover on the syringe Luer connector and attach the safety needle to the Luer Lock of the syringe by twisting.

Transport filled syringe to point of administration.

Pull shield straight off needle to avoid damaging needle point.

Administer injection following instructions above.
For user convenience, the needle 'bevel up' position is orientated to the lever arm, as shown in Figure 3.

Immediately activate needle protection device upon withdrawal from patient by pushing lever arm completely forward until needle tip is fully covered (Figure 2).

Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate, discard immediately into an approved sharps collector.

Activation of the protective mechanism may cause minimal splatter of fluid that may remain on the needle after injection.

For greatest safety, use a one-handed technique and activate away from self and others.

Disposal
Pre-filled syringes are for single use **only**.
Any unused product or waste material should be disposed of in accordance with local requirements.

Figure 1

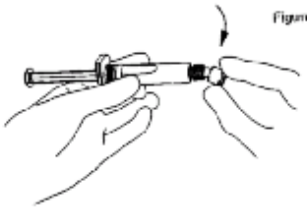

Figure 2

Activated after use

Figure 3